REMARKS

Reconsideration and withdrawal of the rejections of and/or objections to the application are respectfully requested in view of the amendments and remarks herewith

Pursuant to 37 C.F.R. § 1.136(a), Applicants hereby request a one month extension of the term for reply set by the November 21, 2001 Office Action, i.e., up to and including March 21, 2002. Enclosed herewith is a check for $55.00 for a one month extension of time ($55.00) to respond to an official action for a Small entity. The Commissioner is authorized to charge any additional fees to Deposit Account No. 50-0320.

Claims 1-30 are pending. Claims 2, 6, 7, 9 and 16 are cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 1, 3-5, 8, and 10-15 are amended and new claims 17-30 are added without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims, as originally presented, and as herewith presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. Changes to claims and/or new claims as presented herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Applicants enclose as separate documents both the PTO-1449 and the corresponding Information Disclosure Statement as requested by the Examiner for the references cited in the International Search Report.

Claims 1-16 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

The amended recitations to claims 1-3, 5, 7-14, the cancellation of claim 9, and the addition of new claims 17-30, made without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, have rendered the instant rejections moot.

Consequently, the Section 112, second paragraph, rejection should be reconsidered and withdrawn; and, such relief is respectfully requested.

Claim 16 is cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents thereby obviating the rejection under 35 U.S.C. 101.

Claims 1-4, 6-12, 14 and 16 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by WO 95/24172. The rejection is traversed.

The Examiner alleges that WO 95/24172 discloses a transdermal delivery system which has a backing (cover layer), a pressure sensitive adhesive drug composite layer, and a release liner (protective layer), a gelled drug layer containing hydroxycellulose between two active-free adhesive layers and a backing and release liner that are made of silicon polyester. The Examiner further asserts that WO 95/24172 (hereafter referred to as "the '172 patent") allegedly reads on the instantly claimed thickness and that WO 95/24172 teaches the use of the device for nicotine withdrawal. The amendment of claim 1 has rendered this rejection moot.

The present invention is directed to, *inter alia* a transdermal system consisting of: a) a cover layer, b) an active-ingredient containing polymer layer, c) optionally active-ingredient-containing adhesive layers,
and d) a protective layer, wherein the active-ingredient-containing polymer layer comprises water-soluble polymers and the active ingredients are present in the polymer layer in the form of (an) active ingredient solution(s) or dispersion(s) which are not miscible with water.

The '172 patent fails to disclose, teach or suggest the present invention.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Thus, applying the law to the instant facts, it is clear that the '172 patent does not anticipate the Applicants' invention. The '172 patent does not contain all of the elements of the instant claims, e.g., an active-ingredient-containing polymer layer which comprises water-soluble polymers and the active ingredients which are present in the polymer layer in the form of (an) active ingredient solution(s) or dispersion(s) which are not miscible with water. Accordingly, the Office Action failed to meet its burden in showing that the '172 patent contains every limitation of the rejected claims.

To wit, the '172 patent does not disclose, suggest or motivate a skilled artisan to, *inter alia*, prepare the transdermal system of the present invention. The '172 patent does not disclose each and every claimed element of Applicants' invention and consequently the '172 patent is not a proper anticipatory reference.

Consequently, withdrawal of the Section 102(b) rejection is believed to be in order and such action is respectfully requested.

Claim 13 is rejected under 35 U. S. C. §103(a) as being unpatentable over WO 95/24172. The rejection is traversed.

Claim 14 is rejected under 35 U. S. C. §103(a) as being unpatentable over WO 95/24172 in view of Sweet et al. (U.S. Patent No. 4,882,377). The rejection is traversed.

Claims 5 and 15 are rejected under 35 U. S. C. §103(a) as being unpatentable over WO 95/24172 in view WO 89/07959. The rejection is traversed. These rejections shall be addressed collectively.

The Examiner alleges that WO 95/24172 teaches a transdermal delivery system and allegedly discloses materials that may be used in the adhesive layer such as polyurethane, the use of silicon elastomers, nitroglycerin as an active ingredient or the system to be used to treat Angina pectoris. The Examiner acknowledges that the WO 95/24172 does not teach a porous polymer layer or a specific fabric to be used in the adhesive layer or the use of silicon elastomers in the backing or release layer.

The Examiner further alleges that Sweet et al. discloses a pressure-adherent silicon elastomer composition in a transdermal drug delivery patch and allegedly the advantages of using a silicom elastomer such as its ability to maintain tack and cohesivenesss even in moist conditions.

The Examiner also alleges that WO 89/07959 (hereafter referred to as "the '959 patent") teaches an occlusive body patch for transdermal administration of active agents,

the use of a microporous polymer in the active layer and that nitroglycerine may be substituted for nicotine.

Such a specific combination of a transdermal system consisting of: a) a cover layer, b) an active-ingredient containing polymer layer, c) optionally active-ingredient-containing adhesive layers, and d) a protective layer, wherein the active-ingredient-containing polymer layer comprises water-soluble polymers and the active ingredients are present in the polymer layer in the form of (an) active ingredient solution(s) or dispersion(s) which are not miscible with water is not disclosed, taught or suggested by the '172 patent, 'the 959 patent or Sweet et al.

With regard to the Examiner's assertion that it would be obvious to one of ordinary skill in the art at the time the invention was made to use a fabric in the adhesive layer since the art allegedly suggests polyurethane as one of the materials that can be used. Applicants respectfully fail to see how the disclosure of polyurethane in the '172 patent would motivate one of ordinary skill to use a fabric in the adhesive layer of the instant transdermal device. In addition, the '172 patent does not teach or suggest the use of woven or non-woven fabrics in an adhesive layer and therefore the '172 patent provides no motivation to incorporate such woven or non-woven fabrics into the instantly claimed transdermal system.

Applicants respectfully submit as acknowledged by the Examiner, that the '172 patent does not teach or suggest the use of siliconised plastics film or a silicon paper protective layer. In addition, Sweet et al. does not remedy the deficiencies of the '172 since it simply teaches the use of silicone pressure sensitive adhesives and does not teach or suggest siliconised plastics film or a silicon paper protective layer. Consequently the '172 patent provides no motivation to construct or use the protective layer as instantly claimed.

With regard to the Examiner's assertion that one of ordinary skill in the art at the time the invention was made would be motivated to have a microporous polymer in the active layer to control the rate of release and also to use nitroglycerin since the active agent is allegedly dependent on the type of disorder treated and thus would use nitroglycerine, transdermally administered agent to treat Angina pectoris in the transdermal drug system of the '172 patent. Applicants disagree, the '172 patent does not teach or suggest the instantly claimed transdermal system nor would one be motivated to

incorporate a microporous layer into the active layer to control the rate of release. Applicants respectfully submit that the '959 patent teaches a microporous membrane which is simply used to define a cavity between a physiologically active substance in liquid form. In contrast, the transdermal system of the instant invention does not contain such a microporous membrane; instead the polymer layer of the instantly claimed transdermal system is perforated. More specifically the perforations allow the direct contact between the adhesive layer above the polymer layer and the cover layer and adhesive layer below the polymer layer. Therefore the disclosure of a microporous membrane whose function is to define a cavity of a physiologically active substance in liquid form would not motivate one of ordinary skill in the art to incorporate the perforations as instantly claimed.

In addition, Applicants respectfully submit that neither the '172 or the '959 patent teaches or suggests the instant transdermal system and therefore they do not provide any disclosure that would motivate one of ordinary skill in the art to use nitroglycerine to treat angina pectoris in a transdermal drug as instantly claimed.

It is additionally respectfully asserted that it is well settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Holmes does not satisfy the requirements for obviousness. The'172 patent, 'the 959 patent nor Sweet et al. possess the requisite suggestion or disclosure that would lead a skilled artisan to practice, *inter alia*, the instantly claimed transdermal system.

The cited documents, in other words, do not lead a skilled artisan to practice the instant invention.

Consequently, reconsideration and withdrawal of the Section 103 rejections are believed to be in order and such actions are respectfully requested.

Applicants wish to note that included herewith is a change of correspondence address for this application.

Respectfully submitted,

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APPENDIX 1:VERSION TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A transdermal system [comprising] consisting of:

a) a cover layer [(1, 11)],

[b) a water-soluble material that can be dissolved by moisture on the skin]

b) an active-ingredient containing polymer layer,

c) an optionally active-ingredient-containing adhesive [layer (4, 14)],

and

d) a protective layer [that is detachable therefrom],

[the transdermal system being characterised by an] wherein the active-ingredient-containing polymer layer [(3) in which the active ingredient is present in the form of a non-water-miscible active ingredient solution or a non-water-miscible active ingredient dispersion in a] comprises water-soluble [polymer] polymers and the active ingredients are present in the polymer layer in the form of (an) active ingredient solution(s) or dispersion(s) which are not miscible with water.

3. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the active ingredient(s) in the polymer layer [(3)] is (are) not miscible with water.

4. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the [hydrophilic] water-soluble polymer [comprises] is gelatin [or cellulose esters or ethers or derivatives thereof].

5. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the polymer layer [(3)] is perforated, so that at least the adhesive layer [(4)] above the polymer layer can come in to contact with [layers [(1, 2)] the cover layer and the adhesive layer below [disposed on the other side of] the polymer layer [(3)].

8. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the thickness of the adhesive layer [(4)] below the polymer layer is from 10 to 300 μm[, preferably from 30 to 100 μm].

10. (Amended) A process for the manufacture of a transdermal system according to claim 1 [characterised, in that,] wherein in a freely selectable order, an adhesive layer [(4)] is applied to a protective layer [(5)], an active-ingredient-containing polymer layer [(3)] optionally having perforations is applied to the adhesive layer [(4)], a further adhesive layer [(2)] is optionally applied below [to] the polymer layer [(3)], and a cover layer [(1)] is applied to the top layer.

11. (Amended) A transdermal system according to claim 1, [characterised, in that] wherein the cover layer [(1, 11)] comprises one or more water-vapour-impermeable material(s)[, especially polyester, preferably polyterephthalic acid ester, or polypropylene or polyethylene, or one or more water-vapour-impermeable material(s), especially] polyurethane, or one or more woven or non-woven fabrics].

12. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the adhesive layer [(4,14) and/or the adhesive layer (2) are, independently of each other,] is a pressure-sensitive adhesive [layers] layer.

13. (Amended) A transdermal system according to claim 1, [characterised, in that] wherein the adhesive layer [(4, 14) and/or the adhesive layer (2) contain] comprises a net[, a non-woven fabric or a woven fabric, the thread or fibre thickness thereof preferably being less than the thickness of the adhesive layer].

14. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the detachable protective layer [(5, 15) is re-detachable and] is [especially] a siliconised plastics film [or a silicone paper].

15. (Amended) A transdermal system according to claim 1, [characterised in that] wherein the active ingredient [comprises] is testosterone[, nitroglycerine or mixtures thereof].